

Serial No. 10/698,025

**REMARKS**

This is a full and timely response to the outstanding final Office Action mailed September 28, 2007. Reconsideration of the application and allowance of presently pending claims as amended, are respectfully requested.

**A. Present Status of Patent Application**

Upon entry of the amendments in this response, claims 1-13, 16-17, 29-30, 32-39, 41, 43-47 and 49 remain pending in the present application. By this Amendment, Independent claims 1, 29, 32 and 43 have been directly amended, and dependent claims 2-4, 10-13, 16, 17, 30, 33, 36 and 37 also directly amended. Claims 21-25 and 27 have been cancelled without prejudice, waiver or estoppel.

It is believed that the foregoing amendments and additions add no new matter to the present application and no estoppels are intended thereby, and are made to place the claims in condition for allowance or appeal.

The Examiner objected to the quality of the prior set of claims, and requested a clean copy thereof. In response, applicants note that a complete set is transmitted herewith, and readability should be better based upon the larger type font. However, applicants would be happy to transmit (or mail) any further sets of claims, amended or unamended, as the Examiner would like. The Examiner is invited to call the undersigned to request such claim sets as needed.

**B. Response to Action****1. Rejection under 35 U.S.C. §102(b)**

Claims 29 and 30 were rejected under 35 U.S.C. §102(b) as allegedly unpatentable over Martin et al US 5,183,187. This rejection is respectfully traversed.

Martin et al can not anticipate claims 29 and/or 30 for at least the reasons that Martin et al: (1) does not disclose or suggest a pharmaceutical formulation comprising insulin, and (2) does not disclose or suggest a pharmaceutical formulation comprising a propellant. Both of these elements were present in the unamended claims, and as such fully distinguish over Martin et al. Nonetheless, to improve clarity, applicants have

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amended independent claim 29 to recite a first and a second pressurizing means.

Martin et al is inapposite in teaching a fluid dispensing apparatus which operates solely by mechanical action of a piston or plunger fluid driving means. In contrast, applicants claim an apparatus which uses a first and a second pressurization means, which act together to pressurize the contents, and as such patentably distinguishes over the cited art. Claim 30 is additionally patentable as discussed *infra*.

2. Rejections under 35 U.S.C. §103(a)

A. Claims 1-13, 16, 17, 21-25, 27, 32-39 and 41 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Martin et al US 5,183,187. This rejection is respectfully traversed as to the amended claims.

As recited in response to the 102 (b) rejection above, Martin et al is limited to a fluid driving means (plunger or piston) which is entirely and solely mechanical in nature, requiring application of an external energy source to effect the fluid dispensing. In contrast, even applicants' unamended claims thereby patentably distinguish over Martin et al. However, applicants have amended independent claims 1 and 36 to further clarify this distinction in reciting a first and a second pressurization means.

B. Claims 29-30, 43-47 and 49 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Martin et al US 5,183,187 and further in view of Riebe et al, US 6,644,306. This rejection is respectfully traversed as to the amended claims.

The deficiencies of Martin et al as a basis for this rejection have been described in paragraphs 1 and 2 above. The Riebe et al reference adds nothing to Martin et al, because Riebe et al is limited to teaching a simple valve, suitable for an aerosol container. Riebe et al is devoid of any teaching or suggestion of an aerosolization apparatus and/or method of aerosolizing a pharmaceutical formulation, and in particular does not teach, suggest or disclose such an apparatus having a first and second pressurizer.

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Moreover the combination of Riebe et al with Martin et al is improper for the simple reason that that the two describe redundant approaches. Martin et al pressurizes fluid with a piston, thus no independent valve is necessary; rather, the piston is both pressurizing means and means for metering out the fluid. Riebe et al represents the opposing approach, that is, a fluid propellant pressurizes a liquid within a chamber, which pressurized fluid is released by a valve. Thus, there is no teaching, suggestion or motivation to combine the two since the result would be the redundant aggregation of a piston-operated fluid dispensing means with a valve atop the dispenser.

With respect to each of the above rejections as applied to the dependent claims, as the independent claims are allowable over the prior art of record, then their dependent claims are allowable as a matter of law, because these dependent claims contain all features/elements/steps of their respective independent claim. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the foregoing reasons for the allowability of the independent claims, the dependent claims recite further features/steps and/or combinations of features/steps (as is apparent by examination of the claims themselves) that are patentably distinct from the prior art of record. Hence, there are other reasons why these dependent claims are allowable.

### Conclusion

In view of the foregoing, Applicants submit that pending claims 1-13, 16-17, 29-30, 32-39, 41, 43-47 and 49 satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all rejections is respectfully requested and a prompt mailing of a Notice of Allowance is solicited.

Please grant any extensions of time required to enter this response and charge any additional required fees to **Deposit Account 50-0348**.

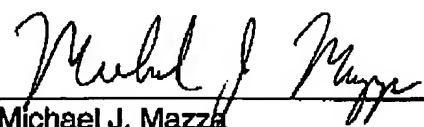
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If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 283-6790.

Respectfully submitted,  
Nektar Therapeutics

Date: 11 Dec 07

By:

  
Michael J. Mazza  
Registration No. 30,775

**CORRESPONDENCE ADDRESS:**

Customer No. 21968

Nektar Therapeutics  
201 Industrial Road  
San Carlos, CA 94070  
(650) 631-3100 (Telephone)  
(650) 620-6395 (Facsimile)